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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,285	03/05/2002	Jay R. Patel	1199486.US	3141

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EXAMINER
SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,285	PATEL, JAY R.	
	Examiner	Art Unit	
	A R Salimi	1648	

-- Th MAILING DATE of this communication appears on the cov r sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed 10/21/2003. Claims 15-22 have been canceled. Claims 6-14 are pending.

Please note any grounds of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract as it was indicated previously is required and has not been received. An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

Claims 6-14 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced in the previous Office Action mailed 7/21/2003. Applicant argues that the limitation of "non-toxic mutagen" are defined in the specification and points to page 2, lines 29-34. In addition, Applicant argues that one of skill in the art would be envision to all comparable non-toxic mutagens from the given example. Moreover, Applicant adds that the scope of the phrase

"non-toxic mutagen" is not limited to the example given, but encompasses what one of ordinary skill in the art would classify as non-toxic mutagen. Regarding the term "about" Applicant argues that term is well known to one of ordinary skill in the art to mean a numerical range, and temperature ranges are well known and understood. Applicant's argument as part of amendment, filed 10/21/2003 has been considered fully, but they are not persuasive. At the onset Applicant is reminded to read the disclosure carefully, since the specification does not list the "non-toxic mutagen" at page 2, lines 29-34. What the disclosure indicates is, without any specificity, the EHV-1 mutants can be obtained at 34 degree C with "**non-toxic concentration of a mutagen**" , and then indicates "such as" "5-bromo-2.., azacytidine and the like during viral replication in vitro." Non-toxic concentration has nothing to do with "non-toxic mutagen", in other words, the mutagen may very well be toxic but it can be used at concentrations that it is not toxic, now what those concentrations are one of ordinary skill in the art cannot know from reading the specification. In addition, the specification is using the term "such as", but there is nothing in the specification that says to one of skill in the art what family of chemicals would be suitable, naming two chemicals that have no relationship with each other and have different structure does not adequately explain the intended metes and bounds of the "mutagen(s)", and that is why the claim is vague and indefinite, since when one reads the specification is not appraised of its boundaries of what compounds or molecules are included or excluded. That is why the Office asked the question is SDS the intended chemical which Applicant mentioned in the response but did not clarify the record. The term is indefinite and the rejection is maintained.

As to the limitation of "about", Applicant makes a contradictory remark, on page 6 of the response Applicant contends that the limitation "about" refers to a numerical range, and on top of page 9 of the response Applicant indicates that "limitation of about does not include 34 degree C", this has to be reconciled. If the term "about" is a numerical range, then what is the range and if it does not include 34 degree C, then what does it include? Since the specification does not set forth a clear "numerical range" for the limitation of "about", and broadest interpretation is given to the claim limitations and since the specification is not clear, then claim is vague and indefinite. Still further, Applicant is reminded although the claim is interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The rejection is maintained.

Claim Rejections - 35 USC § 112

The previous Claim 7 rejection under 35 U.S.C. § 112, first paragraph, is removed only in view of Applicant's deposit statement singed by Mr. Ramey and filed on 11/21/2003.

Claim Rejections - 35 USC § 102

Claims 6, 8, 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Boxall et al (GB 1,570,732) for reasons of record advanced in the previous Office Action mailed 7/21/2003. Applicant argues that one skilled in the art would understand the limitation of about 34 degree C as not including 33 degree C. In addition, Applicant asserts serial passaging is not claimed and non-toxic form of mutagenesis doe snot include serial passaging as is clear from the specification

Applicant's argument as part of amendment, filed 10/21/2003 has been considered fully, but they are not persuasive. First, Applicant's assertion regarding "the limitation of about 34 degree C as not including 33 degree C" is considered to be an unsupported assertion, there is nothing in the specification that would indicate the limitation of "about" does not include 33, it certainly does not excludes it. The limitation of "about" is a relative term, which is subject to varied interpretation, and there is nothing in the specification to support Applicant's assertion that one of skill in the art would conclude the 33 degree C is not intended within the meaning of "about" limitation. As for serial passaging, the claim is interpreted in light of specification and its clear meaning as it would be interpreted by one of ordinary skill in the art. A normal use of the term is given its proper weight, serial passaging is a non-toxic form of inserting mutagenicity into a virus. The serial passaging is not excluded as a non-toxic form of treating cells during viral replication in vitro. As Applicant asserted on page 5 of the response " the scope of the phrase non-toxic mutagen is not limited to the example given, but encompasses what one of ordinary skill in the art would classify as non-toxic mutagen." Well one of ordinary skill in the art would consider serial passage as non-toxic form of inserting mutagenicity in a virus. The rejection is respectfully maintained.

Claim Rejections - 35 USC § 103

Claims 6, 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boxall et al (GB 1,570,732) and Halle Sidney (Journal of Virology, Oct. 1968, pages 1228-1229) for reasons

of record advanced in the previous Office Action mailed 7/21/2003. Applicant argues that the examiner has used hind sight reconstruction to establish obviousness, and the Office has failed to state a motivation to combine the teaching. Applicant concludes that the cited articles do not provide suggestion or motivation and the rejection is impermissible. Applicant's argument as part of amendment, filed 10/21/2003 has been considered fully, but they are not persuasive. The assertion that the rejection made by the examiner was based on hindsight reconstruction is misplaced. The examiner would like to bring to the attention of the Applicant that "any judgement on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." In re McLaughlin 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). In this case Boxall et al had already provided ample teaching towards a process of producing an attenuated temperature sensitive equine herpesvirus (see the claims), this is the same virus that Applicant has used. In addition, Halle taught the mutagenic effect of 5-Azacytidine wherein incubation of a virus with the said mutagen would render a mutation. What other information beside routine experimentation is needed to obtain the claimed invention? In view of the above cited art at the time of filing one of ordinary skill in the art would not have anticipated any unexpected results, as none have been provided. It is rather interesting that in every aspect of the invention Applicant is relying on the skill of those ordinary skill in the art to know, understand, and enable the claimed invention with no difficulty. And yet

under obviousness statute, Applicant is indicating that "skill in the art" does not act as a bridge. This has to be reconciled. As it was stated previously one of ordinary skill in the art at the time of filing would have been highly motivated to produce temperature sensitive equine herpesvirus to be utilized in vaccine production. The above cited art taught a method of producing temperature sensitive of equine herpesvirus as taught by Boxall et al, and a chemical mutagen that can be used to insert a mutation within the virus genome as taught by Halle. One of ordinary skill in the art at the time of filing being familiar with above cited art would not have anticipated any unexpected results as none have been provided. This is a situation of obvious to try and obvious to succeed. Therefore, the invention as a whole is ***prima facie*** obvious absent unexpected results. The rejection is maintained.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

1/1/2004